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Section 5

510k Summary

MAY - 1 2008

Name:	Speciality Fibres & Materials Limited
Address:	101 Lockhurst Lane, Coventry CV6 5RS, U.K.
Telephone:	011 44 2476 708200
Fax:	011 44 2476 682737
e-mail	colin.ludford@sfm-limited.com
Contact Person:	Colin Ludford, Operations Director
Date:	30th April 2008
Trade Name:	**Suprasorb® A + Ag**
Common Name:	As Trade Name
Classification Name:	Dressing
Classification	There is currently no classification for this device
Predicate Devices	Absorbent Antimicrobial Wound Dressing (Aquacel Ag) 510(k) No. K013814 Antimicrobial Alginate Dressing (Maxorb Extra Ag), 510(k) No. K041316
Description of the device	Calcium Alginate Dressing with Antibacterial Silver

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Intended use:	**Suprasorb® A +Ag** Calcium Alginate Dressing with Antibacterial Silver can be used for the management of wounds which are: • Moderate and heavily exuding • Superficial or • Deep such as: • Pressure sores • Arterial Ulcers • Venous lower leg ulcers • Diabetic ulcers • Post-operative wounds
Product description	Suprasorb® A + Ag Calcium Alginate Dressings with Antibacterial Silver are soft, conformable wound covers with a high mannuronic acid content. The silver-impregnated calcium alginate fibres, when in contact with wound exudate or blood, form a gel which creates a moist wound healing environment. The silver in the wound dressing has an antibacterial effect upon various types of bacteria including *Staphylococcus aureus* and *Escherichia Coli*. The silver ions protect the dressing from a broad spectrum of bacterial contamination over a period of up to 3 days in the in vitro challenge test. Suprasorb® A + Ag Calcium Alginate Dressings with Antibacterial Silver are sterilized by irradiation and must not be re-sterilized. The products are sterile unless the package is opened or damaged. Suprasorb® A + Ag Calcium Alginate Dressings with Antibacterial Silver are for single use only.
Performance data	The biocompatibility of Speciality Fibres and Materials Limited's **Suprasorb® A + Ag** has been demonstrated in accordance with ISO 10993-1 and the FDA Blue Book memorandum #G95-1. Results were equivalent to those for the predicate devices In vitro testing for silver content, silver release and absorbency, gave similar results to the predicates.

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Statement of substantial equivalence	**Suprasorb® A + Ag** Calcium Alginate Dressing with Antibacterial Silver is substantially equivalent in construction and performance to both the Aquacel Ag (K013814) and **Maxorb** Extra Ag (K041316) predicate devices. Comparable biocompatibility, cytotoxicity, absorbency and silver release results have been demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Specialty Fibres and Materials, Ltd.
% Mr. Colin Ludford
P.O. Box 111
101 Lockhurst Lane
Coventry
United Kingdom CV6 5RS

MAY - 1 2008

Re: K071442
Trade/Device Name: Suprasorb® A +Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 2, 2008
Received: April 15, 2008

Dear Mr. Ludford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071442

Section 4

Indications for Use

510(k) Number (if known):- K071442

Device Name: **Suprasorb® A +Ag**

Indications for Use: **Suprasorb® A +Ag** Calcium Alginate Dressing with Antibacterial Silver can be used for the management of wounds which are:

- Moderately and heavily exuding
- Superficial or
- Deep

Such as:

- Pressure sores
- Arterial Ulcers
- Venous lower leg ulcers
- Diabetic ulcers
- Post-operative wounds

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071442